

In re Application of: Alexei SHIR et al  
Serial No.: 10/535,189  
Filed: September 21, 2006  
Office Action Mailing Date: December 27, 2007

Examiner: Terra C. Gibbs  
Group Art Unit: 1635  
Attorney Docket: 29770

### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 72-98 are in this case. Claims 72-95 have been withdrawn under a restriction requirement for a non-elected invention. Claims 96-98 have been rejected under 35 U.S.C. § 112 and under 35 U.S.C. § 102. Claim 96 has now been amended. New claims 99-109 have now been added.

#### ***35 U.S.C. § 112 Rejection***

The Examiner has rejected claims 96-98 under 35 U.S.C. § 112 as being indefinite. Specifically, the Examiner states use of the term "selected" in Claim 96 renders the claim grammatically incorrect.

Claim 96 has now been corrected to remove the term "selected", thereby rendering the Examiner's rejection moot.

#### ***35 U.S.C. § 102(a) Rejection***

The Examiner has rejected Claims 96-98 as being anticipated by Abounader et al (FASEB Journal 2002, Jan; 16(1):108-10; Epub 2001 Nov 29).

The Examiner states that Abounader et al teach in vivo targeting of scatter factor/hepatocyte growth factor and/or c-met expression via U1snRNA/ribozymes in glioma cells. The Examiner further states that administration of the disclosed ribozymes brings about programmed cell death or apoptosis, thereby anticipating claims 96-98.

The Examiner has also rejected Claims 96-98 as being anticipated by Czubzuko et al (Proc. Natl. Acad. Sci., 1996 Vol 93: 14753-14758).

The Examiner states that Czubzuko et al teach cell death by a ribozyme targeted to the secreted growth factor pleiotrophin.

The Examiner has further rejected Claims 96-98 as being anticipated by Zhao et al (Development, 1998 Vol. 125:1899-1907).

The Examiner states that Zhao et al disclose retinal cell death by a ribozyme construct targeted to neuregulin-1.

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The Examiners rejections are respectfully traversed.

Applicant wishes to point out that the compositions for cell killing of the present invention rely on double stranded RNA which is cytotoxic to all cells. In sharp contrast to the cell killing of Abounader et al, Czubyko et al and Zhao et al, selective cell killing is brought about by the use of specific targeting moieties on carrier molecules comprising the double stranded RNA. The teachings of Abounader et al, Czubyko et al and Zhao et al, do not hint at, or suggest using such targeting moieties since ribozyme selectivity lies in the ribozyme itself and no further targeting moiety is required. To elaborate, ribozyme selectivity relies on down-regulation of RNA molecules which are specifically expressed in target cells. Cells which do not express the RNA molecule which is specifically targeted by the ribozymes will therefore not be affected.


To differentiate the present invention from those using ribozymes, Claim 96 has now been amended such that the association of the targeting moiety is limited to the nucleic acid carrier and not the RNA molecule itself.

Support for such an amendment may be found throughout the present specification – see for example page 20 lines 21-28.

New claims 99-109 have been added to further limit the composition-of – matter used in the present invention for cell killing. All claims are fully supported in the text, such that no issue of new matter arises. Specifically, Claims 99-107 correspond to Claims 80-88 and Claims 108-109 correspond to 77-78.

In view of the above amendments and remarks it is respectfully submitted that claims 96-109 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

  
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Date: April 27, 2008

**Encl:**  
Petition for Extension (1 Month)  
Additional Claims Transmittal Fee